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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/175,713	10/20/98	HERRMANN S	GI-5302-CON

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LEGAL AFFAIRS
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EXAMINER	
ANDRES, J	
ART UNIT	**PAPER NUMBER**
1646	8

DATE MAILED: 08/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/175,713	HERRMANN ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) 15,16 and 19-47 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14,17 and 18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Claims 1-47 are pending in this application. Applicant's election of Group I, claims 1-14, 17, and 18 in paper number 7, filed May 16, 2000, and telephonic species election of SDF-1 alpha by Kymne Hehman on August 8, 2000 is acknowledged. Claims 15, 16, and 19-47 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

1. The disclosure is objected to because of the following informalities: The first paragraph contains errors. The serial number of the provisional application to which priority is claimed is not correct, nor is the continuity data. The correct serial number is 60/113672 and it was converted from an application that was a continuation in part of 08/808720.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 17, and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5, 10-14, 17, and 18 are drawn to a genus, i.e polynucleotides encoding amino-terminal modified chemokines. Applicant has disclosed the functional characteristics of one species, met-SDF-1 beta, which exhibits an enhanced function relative to the native molecule, but has not disclosed sufficient species for the broad genus of any amino-terminal modified chemokine. The disclosure of this one member is insufficient to describe this genus. The disclosed species demonstrates enhanced function as compared to the previously described, naturally produced chemokine, but applicant has not described the features of amino-terminally modified chemokines crucial to the this enhancement of function, such as specific structural or functional characteristics, and allowed modifications, that would identify the modified SDF-1 beta as being representative of a genus of amino-terminally modified chemokines. Claims 1-14, 17, and 18 encompass sequences comprising polynucleotides encoding amino-terminal modified chemokines and claims 6-9 additionally encompass sequences encoding fragments of modified chemokines. However, since the required structural and functional characteristics of the claimed genus have not been described, there is no way to determine what additional sequences would be tolerated for a given polynucleotide comprising one of the claimed sequences to be identifiable as a member of this genus. There is thus insufficient guidance regarding structural features that could identify other species in the claimed genus and one of skill in the art would reasonably

conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claims 1-14, 17, and 18 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding met-SDF-1 beta, does not reasonably provide enablement for any other amino-terminally modified chemokines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

As written, claims 1, 2, 5, 10-14, 17, and 18 encompass any change to the amino terminus of the listed chemokines, including additions, deletions, and substitutions. Claims 3 and 4 are drawn to specific modifications. Claims 6-9 are drawn to sequences comprising specific sequences, as well as sequences comprising fragments of these sequences, and complements. Claims 17 and 18 include further functional limitations. However, applicant has not described the structural features or functional characteristics that would enable one of skill to make and use polynucleotides encoding amino-terminally modified polypeptides other than met-SDF-1-beta, including

sequences comprising this or any other sequence. The amino acid sequence of an encoded polypeptide determines its structural and functional properties, and predictability of what effect additions will have is complex and well outside the realm of routine experimentation, because accurate predictions of a polypeptide's structure from mere sequence data are limited. In the instant case, it is known that the addition of a methionine residue (Proudfoot et al., J. Bio. Chem. Vol. 271, 2599-2603, 1996) can produce an antagonist, as is observed for RANTES, or an agonist, as is observed for SDF-1beta as taught in the instant specification, and thus it is known that the effect of even a single defined amino-terminal modification is unpredictable, and the claims encompass many modifications. Thus many molecules are potentially within the scope of the claims, but the characteristics of these molecules are not predictable. There is no guidance in the specification as to what changes could be made without altering the characteristics of the claimed molecules, nor, as discussed above, would the effect of any alteration be predictable without such guidance. While recombinant techniques are available, it is not routine in the art to screen large numbers of substituted proteins where the expectation of obtaining similar activity is unpredictable based on the instant disclosure. Thus it would require undue experimentation for the skilled artisan to practice the invention commensurate with the scope of the claims.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the laboratory names in claims 1-5, dependent claims 10-14, and claims 17 and 18 is vague and indefinite because the proteins are only described by arbitrary names or the designation "chemokine". While the names themselves may have some notion of the activity of the proteins, there is nothing in the claims that distinctly identifies the proteins. Others in the field may isolate the same proteins and give them entirely different names or give the same names to a different protein. Applicant should particularly point out definitive characteristics associated with the proteins and refer to them by the numbers of entered sequences. Describing biochemical molecules by a particular name given to a protein or class of proteins by various workers in the field fails to distinctly identify what the protein is.

Claims 1, 2, 6-14, 17, and 18 are indefinite in the recitation of "amino-terminal-modified". This term could encompass additions and deletions of any length, as well as substitutions, and thus the metes and bounds of this phrase are not clearly set forth in the claims.

Claims 6-9 are indefinite in the recitation of "amino-terminal fragment" and of "hybridizing under stringent conditions". Applicant has not described the length or specific characteristics of a "fragment" that would meet the limitations of the claims. "Stringent conditions" have not been also described in the specification and thus one of skill in the art would not be able to determine what polynucleotides would be considered

to bind stringently, how long the polynucleotides might be, and whether applicant intended the claims to encompass complements to native chemokines, which would meet the limitations of the claim as written.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1, 5 and10-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Pelus et al., U.S. patent no. 6080398, which claims priority to 1993 and Talmadge, U.S. patent no. 5627156, filed 1994. Pelus et al. (see the whole document) teaches amino terminal truncations of Gro having enhances bioactivity. Talmadge teaches N-terminally modified interleukin-8 peptides (column 4, lines 25-53). Since applicant includes "any kind of alteration, addition, insertion, deletion, mutation, substitution, replacement, or other modification" (page 17) in the definition of "amino-terminal-modified-chemokine", these truncations are within the scope of the instant claims.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Proudfoot et al., J. Biol. Chem. Vol. 271, pp. 2599-2603, February 2, 1996. Proudfoot et al.(see the whole document) teaches the production of a RANTES antagonist by retention of the initiating methionine and therefore anticipates the instant claim of polynucleotides encoding amino-terminal modified chemokines wherein the chemokines are selected from a group including RANTES.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via internet email regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**yvonne.eyler@uspto.gov**].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35

U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet L. Andres, Ph.D.
August 11, 2000

Yvonne Eyler
YVONNE EYLER, PH.D
PRIMARY EXAMINER